NATIONAL MARROW DONOR PROGRAM®

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October 31, 2012

CDR Sheri Parker
Office of Naval Research (ONR 342)
875 N. Randolph St.
Arlington, VA 22203-1995

Subject: **Quarterly Performance/Technical Report of the National Marrow Donor Program®**

Reference: Grant Award #N00014-12-1-0142 between the Office of Naval Research and the National Marrow Donor Program

Dear Cdr. Parker:

Enclosed is subject document which provides the performance activity for each statement of work task item of the above reference for the period of July 1, 2012 to September 30, 2012.

Should you have any questions as to the scientific content of the tasks and the performance activity of this progress report, you may contact our Chief Medical Officer – Dennis L Confer, MD directly at 612-362-3425.

With this submittal of the quarterly progress report, the National Marrow Donor Program has satisfied the reporting requirements of the above reference for quarterly documentation. Other such quarterly documentation has been previously submitted under separate cover.

Please direct any questions pertaining to the cooperative agreement to my attention at 612-362-3403 or at cabler@nmdp.org.

Sincerely,

Carla Abler-Erickson

Carla Abler-Erickson, MA
Contracts Manager

Enclosure: Quarterly Report with SF298

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14. ABSTRACT

1. Contingency Prepardness: Collect information from transplant centers, build awareness of the Transplant Center Contingency Planning Committee and educate the transplant community about the critical importance of establishing a nationwide contingency response plan.

2. Rapid Identification of Matched Donors : Increase operational efficiencies that accelerate the search process and increase patient access are key to preparedness in a contingency event.

3. Immunogenetic Studies: Increase understanding of the immunologic factors important in HSC transplantation.

4. Clinical Research in Transplantation**:** Create a platform that facilitates multicenter collaboration and data management.

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Research in HLA Typing, Hematopoietic Stem Cell Transplantation and Clinical Studies to Improve Outcomes

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NATIONAL MARROW DONOR PROGRAM®

Creating Connections. Saving Lives.™

Grant Award N00014-12-1-0142

DEVELOPMENT OF MEDICAL TECHNOLOGY FOR CONTINGENCY RESPONSE TO MARROW TOXIC AGENTS

QUARTERLY PERFORMANCE / TECHNICAL REPORT

FOR

JULY 01, 2012 to SEPTEMBER 30, 2012

PERIOD 3

Office of Naval Research

And

The National Marrow Donor Program
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IIA. Contingency Preparedness – Objective 1: Recovery of casualties with significant myelosuppression following radiation or chemical exposure is optimal when care plans are designed and implemented by transplant physicians	
IIA.1 Task 1: Secure Interest of Transplant Physicians	**Period 3 Activity:** • 26 RITN center staff (including 9 physicians or physician multipliers) attended Advanced Medical Radiation Response training on July 16-17, 2012 at the Radiation Emergency Assistance Center and Training Site in Oakridge, TN (a total of 181 RITN staff have completed this training)
IIA.1 Task 2: GCSF in Radiation Exposure	**Period 3 Activity:** • No activity this period.
IIA.1 Task 3: Patient Assessment Guidelines and System Enhancements	**Period 3 Activity:** • No activity this period.
IIA.1 Task 4: National Data Collection Model – This task is closed.	
IIA. Contingency Preparedness – Objective 2: Coordination of the care of casualties who will require hematopoietic support will be essential in a contingency situation.	
IIA.2 Task 1: Contingency Response Network	**Period 3 Activity:** • 98% of 65 RITN centers completed all of their tasks on time, one requested an extension and five were inactive due to competing priorities (e.g. HIS implementation and FACT Accreditation) o A total of five (5) new hospitals have joined RITN this year including: ▪ University of UT-Primary Children's ▪ Westchester (NY) ▪ Massachusetts General ▪ West Virginia University Hospital ▪ Mount Sinai (NY)

	• RITN participated in the BARDA Medical Countermeasures Capacity review in the National Capital Region and New York City • RITN participated in the FDA Public Workshop; Use of Computer Simulation of the United States Blood Supply in Support of Planning for Emergency Preparedness and Medical Countermeasures • Continued to develop relationships with the National Association of County and City Health Officials (NACCHO), the Association of State and Territorial Health Officials (ASTHO) and the Federal Emergency Management Agency (FEMA) • Conducted a drill of submitting the RITN Capabilities Report through the HealthCareStandard software system • Conducted the monthly RITN Center conference call to review task completion status and allow a venue for centers to talk to peers • RITN Medical Advisor activity; Dr. Weinstock participated in the following activities supporting the Radiation Injury Treatment Network: o He met with representatives from the Veterans Administration and Department of Health and Human Services to establish links with RITN o He was invited to speak at the BARDA symposium on blood products in November 2012 o He is leading the RITN effort to secure a contract with BARDA to establish a user managed inventory system at RITN centers o He updated pediatric and adult template admission orders for casualties of a radiation incident. These are national treatment guidelines for patient management and are posted on the REMM (National Library of Medicine) and RITN websites o He was invited to author a chapter on Radiation Emergency Response in the forthcoming: Koenig & Schultz's Disaster Medicine: Comprehensive Principles & Practice textbook o He coordinated a response framework between RITN and REAC/TS for future radiation events.

IIA.2 Task 2: Sibling Typing Standard Operating Procedures	**Period 3 Activity:** • No activity this period.
IIA. Contingency Preparedness – Objective 3: NMDP's critical information technology infrastructure must remain operational during contingency situations that directly affect the Coordinating Center.	
IIA.3 Task 1: I.S. Disaster Recovery – This task is closed.	
IIA.3 Task 2: Critical Facility and Staff Related Functions	**Period 3 Activity:** • Conducted the 2012 Business Continuity Exercise; 79 staff worked from remote locations not operated by the NMDP to test their ability to use the VPN service as well as to verify the recently upgraded VPN server could handle a significant load; server load monitoring software recorded that the server was at 25% capacity. • Conducted a Business Continuity Site Visit of the NMDP offices in Oakland, CA, Rochester, PA, Spokane, WA, Richmond, VA, Portland, OR and St. Petersburg, FL
IIB. Rapid Identification of Matched Donors – Objective 1: Increasing the resolution and quality of the HLA testing of volunteers on the registry will speed donor selection.	
IIB.1 Task 1: Increase Registry Diversity	**Period 3 Activity:** **Recruitment Typing** • 6 laboratories provided HLA typing on a total of 1,907 newly recruited donors. o 3 laboratories performed HLA-A, B, DRB1 typing o 3 laboratories performed HLA-A, B, C, DRB1 and DQB1 typing o 1 laboratory performed HLA-A, B, C, DRB1, DQB1 and DPB1 typing • The blind quality control testing error rate was 0.24%, meeting the project requirement of ≤ 2.0%. • On-time testing completion rate was 98.6%, meeting the project requirement of a minimum of 90% of typing results reported within 14 days of shipment of samples.

	Rare allele typing project • In the process of typing and confirming rare alleles, certain patterns became evident that indicated when a sample was likely incorrectly reported. These patterns included 1.) allele reported in multiple race groups or allele reported in race group that differed from the IMGT/HLA submission, 2.) allele reported with a second rare or uncommon allele, and 3.) allele frequently reported before 2004 and infrequently reported after that date. Using these guidelines, uncommon alleles in 384 samples stored at the repository were selected for typing at either intermediate or high resolution typing. To date, 76% of the results came back a different allele. • Typing continued on a small group of remaining questionable rare alleles. Eight samples were sent for high resolution typing and five of the samples came back a different allele; three of the samples were confirmed.
IIB.1 Task 2: Evaluate HLA-DRB1 High Res typing – This task is closed.	
IIB.1 Task 3: Evaluate HLA-C Typing of Donors – This task is closed	
IIB.1 Task 4: Evaluate Buccal Swabs	**Period 3 Activity:** **Alternate Sample Collection Methods Study** • Purified DNA from 3 sample collection formats (Oragene saliva collection kit from DNA Genotek, CEP-Swab ejectable-tip swab from Fitzco, and the standard NMDP cotton-tipped swab) have been stored in a room-temperature stable dry format (GenTegra tubes from GenVault). • Sample sets derived from 10 individuals have been sent for Whole Genome Amplification (WGA) of the stored DNA. WGA DNA will be returned as both frozen aliquots and as dry aliquots in GenTegra tubes. Samples will be returned next quarter and then distributed for HLA typing evaluation.
IIB.1 Task 5: Enhancing HLA Data for Selected Donors – This task is closed.	

IIB.1 Task 6: Maintain a Quality Control Program	**Period 3 Activity:** During this quarter, 6 cell lines were received from the cell processing laboratory and incorporated into the regular QC rotation, bringing the total number of active buccal B-LCL QC master lots to 497. Of the 65 cells lines selected for incorporation into the QC program in FY2012, 29 (45%) have exhibited negative cell growth, and another 3 have poor progression. Thirty-five replacement cells were shipped for B-LCL cell initiation/transformation/culture/expansion in September. These samples ensure that the NMDP QC inventory has complete coverage of all CWD alleles with a count greater than 1:10,000 and expand alleles that were depleted to an n of 1. In addition, the majority of CWD alleles with a minimum count of 25 by sequenced based typing methods will now be represented. An error in the sequence of C*02:09 was discovered through the NMDP QC program. As a result, this allele will be deleted in the IMGT/HLA database.
IIB. Rapid Identification of Matched Donors – Objective 2: Primary DNA typing data can be used within the registry to improve the quality and resolution of volunteer donor HLA assignments.	
IIB.2 Task 1: Collection of Primary Data	**Period 3 Activity:** • No activity this period.
IIB.2 Task 2: Validation of Logic of Primary Data – This task is closed.	
IIB.2 Task 3: Reinterpretation of Primary Data – This task is closed.	
IIB.2 Task 4: Genotype Lists & Matching Algorithm	**Period 3 Activity:** The Bioinformatics Research Advisory Ginger Group met on Sept 21, 2012. 15 external advisors and a number of staff employees discussed a range of topics including KIR, ancestry typing and data standards. This group meets twice per year to review the scientific and strategic direction of the Bioinformatics Research department and all activity carried out pursuant to the goals of this research grant.

IIB. Rapid Identification of Matched Donors – Objective 3: Registry data on HLA allele and haplotype frequencies and on the nuances of HLA typing can be used to design computer algorithms to predict the best matched donor.	
IIB.3 Task 1: Phase I of EM Haplotype Logic	**Period 3 Activity:** • No activity this period.
IIB.3 Task 2: Enhancement of EM Algorithm	**Period 3 Activity:** • No activity this period.
IIB.3 Task 3: Optimal Registry Size Analysis	**Period 3 Activity:** • No activity this period.
IIB.3 Task 4: Target Under- Repre-sented Phenotypes	**Period 3 Activity:** • Carried out preparatory statistical model building on donor demand models, as well as donor availability models • Development of Genetic Ancestry educational session for annual meeting
IIB.3 Task 5: Bioinformatics Web Site – This task is closed.	
IIB.3 Task 6: Consultants to Improve Algorithm – This task is closed.	
IIB.3 Task 7: Population Genetics – This task is closed.	
IIB.3 Task 8: Haplotype Matching – This task is closed.	
IIB.3 Task 9: Global Haplotype/Benchmark – This task is closed.	

IIB. Rapid Identification of Matched Donors – Objective 4: Reducing the time and effort required to identify closely matched donors for patients in urgent need of HSC transplants will improve access to transplantation and patient survival in the context of a contingency response and routine patient care.	
IIB.4 Task 1: Expand Network Communications – This task is closed.	
IIB.4 Task 2: Central Contingency Management	**Period 3 Activity:** • NMDP provided support for donor/cord blood unit identification, selection and collection for the NIH intramural unrelated donor transplant program. Activity in the last quarter was as follows: o 3 formal searches o 34 donor confirmatory typing blood sample and IDM testing requests o 10 cord blood unit confirmatory typing requests o 1 cord blood unit, 3 PBSC collections and 2 therapeutic stem cell collections
IIB.4 Task 3: Benchmarking Analysis – This task is closed	
IIB.4 Task 4: Expand Capabilities of Collection and Apheresis Centers – This task is closed.	
IIC. Immunogenetic Studies – Objective 1: HLA mismatches may differ in their impact on transplant outcome, therefore, it is important to identify and quantify the influence of specific HLA mismatches. In contingency situations it will not be possible to delay transplant until a perfectly matched donor can be found.	
IIC.1 Task 1: Donor Recipient Pair Project	**Period 3 Activity:** Donor Recipient Pair Project In 1994 a retrospective D/R Pair HLA typing project to characterize class I and class II alleles of donor/recipient paired samples from NMDP's Repository was initiated. The goals of this ongoing research project are to assay the impact of DNA-based HLA matching on unrelated donor transplant outcome, develop strategies for optimal HLA matching, evaluate the impact of matching at alternative HLA loci on transplant outcome and finally to promote the development of DNA-based high resolution HLA typing methodologies. Presence/absence typing of 14 KIR loci (2DL1-5, 2DS1-5, 3DL1-3 and 3DS1) has been included. • SG27, SG 28 and SG 29 HLA and KIR were audited during this period.

	• SG30 period of performance came to a close on September 30th, 2012. • KIR discrepancy and no make resolution are ongoing. • KIR linkage analysis was received from the typing labs and updates were made in the data base. • The KIR manuscript including the high resolution KIR typing project data was accepted for publication in PLoS One. Publication should occur next quarter. To date over 2500 pairs and 1180 additional donors have been typed for presence/absence of 14 KIR loci (2DL1-5, 2DS1-5, 3DL1-3 and 3DS1).
IIC. Immunogenetic Studies – Objective 2: Even when patient and donor are HLA matched, GVHD occurs so other loci may play a role.	
IIC.2 Task 1: Analysis of non-HLA loci	**Period 3 Activity:** • Developed rigorous quality assurance tests for IIDB, which is a combined repository for infusion outcomes data for research purposes. • Periodically functionally test IPR's interface as new features are implemented into the suite. • Developed new functionality for exporting IPR reports. • Worked on Audit Tool and Audit Report.
IIC.2 Task 2: Related Pairs Research Repository – This task is closed.	
IIC.2 Task 3: CIBMTR Integration – This task is closed.	
IID. Clinical Research in Transplantation – Objective 1: Clinical research in transplantation improves transplant outcomes and supports preparedness for a contingency response.	
IID.1 Task 1: Observational Research, Clinical Trials and NIH Transplant Center	**Period 3 Activity:** • Monitoring activities continued at for the Double Cord Blood clinical trial during this quarter. A total of four monitoring trips occurred at four separate sites. • Amended documents associated with the long-term donor follow up study were translated to Spanish.

IID.1 Task 2: Research with NMDP Donors – This task is closed.	
IID.1 Task 3: Expand Immuno-biology Research	**Period 3 Activity:** The CIBMTR IBWC met monthly during the quarter to discuss progress on ongoing research studies • Three abstracts were submitted: o Joseph Pidala, et al., *Amino acid substitution at peptide-binding pockets of HLA Class I molecules adversely impacts hematopoietic cell transplantation outcomes.* Oral presentation 2012 ASH annual meeting o Fabio Giglio, et al., *Donor KIR3DL1 and HLA-B allotypes control leukemia relapse after allogeneic hematopoietic stem cell transplantation.* Oral presentation 2012 ASH annual meeting o Susana Marino, et al., *Identification of high risk HLA Class I amino acid substitution in hematopoietic stem cell transplantation.* Poster presentation 2012 ASH annual meeting. • Three manuscripts were submitted: o Christiane Dobbelstein, et. al, *Birth order and transplant outcome in HLA-identical sibling stem cell transplantation – an analysis on behalf of the CIBMTR.* Submitted to Haematologica o Effie Petersdorf, et al., *Increasing the safety of HLA-mismatched unrelated donor hematopoietic transplantation.* Submitted to PNAS. o Fabio Giglio, et. al., *Donor KIR3DL1 and HLA-B subtypes and leukemia control in HLA-compatible allogeneic hematopoietic stem cell transplantation.* Submitted to Nature Genetics. • One manuscript was accepted: o Lawrence Petz, et al., *The cure of HIV infections using cord blood transplantation.* Submitted BBMT.

	• One manuscript was published: o Vanderson Rocha et al., *Effect of HLA-matching recipient to donor non-inherited maternal antigens on outcomes after mismatched umbilical cord blood transplantation for hematologic malignancy.* BBMT. 2012 July 17. [Epub ahead of print]

ACRONYM LIST

AABB	American Association of Blood Banks	HSC	Hematopoietic Stem Cell
ABD	Antigen Binding Domain	IBWC	Immunobiology Working Committee
AFA	African American	ICRHER	International Consortium for Research on Health Effects of Radiation
AGNIS	A Growable Network Information System	IDAWG	Immunogenomics Data Analysis Working Group
AML	Acute Myelogenous Leukemia	IDM	Infectious Disease Markers
		IHIW	International Histocompatability and Immunogenetics
API	Asian Pacific Islander	IHWG	International Histocompatibility Working Group
AQP	Ancestry Questionnaire Pilot	IPR	Immunobiology Project Results
ARS	Acute Radiation Syndrome (also known as Acute Radiation Sickness)	ICRHER	International Consortium for Research on Health Effects of Radiation
ASBMT	American Society for Blood and Marrow Transplantation	IND	Investigational New Drug
ASHI	American Society for Histocompatibility and Immunogenetics	IS	Information Services
ATF	Activating Transcription Factor	IT	Information Technology
B-LCLs	B-Lymphoblastoid Cell Lines	IRB	Institutional Review Board
BARDA	Biomedical Advanced Research and Development Authority	JCAHO	Joint Commission on Accreditation of Healthcare Organizations
BBMT	Biology of Blood and Marrow Transplant	KG	Thousand Genomes
		KIR	Killer Immunoglobulin-like Receptor
BCP	Business Continuity Plan	LGPL	Lesser General Public License
		LMS	Learning Management System
BCPeX	Business Continuity Plan Exercise	MDACC	MD Anderson Cancer Center
BMCC	Bone Marrow Coordinating Center	MDHT	Model Driven Health Tools
BMDW	Bone Marrow Donors Worldwide	MDS	Myelodysplastic Syndrome
BMT	Bone Marrow Transplantation	MHC	Major Histocompatibility Complex
BMT CTN	Blood and Marrow Transplant - Clinical Trials Network	MIBBI	Minimum Information for Biological and Biomedical Investigations
BODI	Business Objects Data Integrator	MICA	MHC Class I-Like Molecule, Chain A

BRT	Basic Radiation Training	MICB	MHC Class I-Like Molecule, Chain B
C&A	Certification and Accreditation	MIRIGE	Minimum Information for Reporting Immunogenomic Experiments
CAU	Caucasian	MKE	Milwaukee
CBMTG	Canadian Blood and Marrow Transplant Group	MRD	Minimal Residual Disease
CBB	Cord Blood Bank	MSKCC	Memorial Sloan-Kettering Cancer Center
CBC	Congressional Black Caucus	MSP	Minneapolis
CBS	Canadian Blood Service	MUD	Matched Unrelated Donor
CBU	Cord Blood Unit	NAC	Nuclear Accident Committee
CDA	Clinical Document Architecture	NCBI	National Center for Biotechnology Information
CFU	Colony Forming Units	NCBM	National Conference of Black Mayors
CGI	Common Gateway Interface	NCI	National Cancer Institute
CHORI	Children's Hospital Oakland Research Institute	NGS	Next Generation Sequencing
CHTC	Certified Hematopoietic Transplant Coordinator	NEMO	N-locus Expectation-Maximization using Oligonucleotide typing data
CIBMTR	Center for International Blood & Marrow Transplant Research	NHLBI	National Heart Lung and Blood Institute
CIT	CIBMTR Information Technology	NIH	National Institutes of Health
CLIA	Clinical Laboratory Improvement Amendment	NIMA	Non-Inherited Maternal Allele/Antigen
CME	Continuing Medical Education	NIMS	National Incident Management System
CMF	Community Matching Funds	NK	Natural Killer
COG	Children's Oncology Group	NLE	National Level Exercise
CREG	Cross Reactive Groups	NMDP	National Marrow Donor Program
CSS	Center Support Services	NRP	National Response Plan
CT	Confirmatory Testing	NST	Non-myeloablative Allogeneic Stem Cell Transplantation
CTA	Clinical Trial Application	OCR/ICR	Optical Character Recognition/Intelligent Character Recognition
CTMS	Clinical Trial Management System	OIT	Office of Information Technology
DC	Donor Center	OMB	Office of Management and Budget
DHHS-ASPR	Department of Health and Human Service –	ONR	Office of Naval Research

	Assistant Secretary Preparedness and Response		
DIY	Do it yourself	P2P	Peer-to-Peer
DKMS	Deutsche Knochenmarkspenderdatei	PBMC	Peripheral Blood Mononuclear Cells
DMSO	Dimethylsulphoxide	PBSC	Peripheral Blood Stem Cell
DoD	Department of Defense	PCR	Polymerase Chain Reaction
DHHS-ASPR	Department of Health and Human Services – Assistant Secretary for Preparedness and Response	PSA	Public Service Announcement
DNA	Deoxyribonucleic Acid	QC	Quality control
DR	Disaster Recovery	RCC	Renal Cell Carcinoma
D/R	Donor/Recipient	RCI BMT	Resource for Clinical Investigations in Blood and Marrow Transplantation
DRB	Design Review Board	REAC/TS	Radiation Emergency Assistance Center/Training Site
EBMT	European Group for Blood and Marrow Transplantation	REST	Representational Sate Transfer
EDC	Electronic Data Capture	RFP	Request for Proposal
EFI	European Federation of Immunogenetics	RFQ	Request for Quotation
EM	Expectation Maximization	RG	Recruitment Group
EMDIS	European Marrow Donor Information System	RITN	Radiation Injury Treatment Network
ENS	Emergency Notification System	SBT	Sequence Based Typing
ERSI	Environment Remote Sensing Institute	SCTOD	Stem Cell Therapeutics Outcome Database
FBI	Federal Bureau of Investigation	SG	Sample Group
FDA	Food and Drug Administration	SIRE	Self Identified Race and Ethnicity
FDR	Fund Drive Request	SLCBB	St. Louis Cord Blood Bank
FLOCK	Flow Cytometry Analysis Component	SLW	STAR Link® Web
Fst	Fixation Index	SNP	Single Nucleotide Polymorphism
GETS	Government Emergency Telecommunications Service	SRG	Survey Research Group
GCSF	Granulocyte-Colony Stimulating Factor (also known as filgrastim)	SSA	Search Strategy Advice
GIS	Geographic Information System	SSO	Sequence Specific Oligonucleotides

GL	Genotype List	SSP	Sequence Specific Primers
GNU	GNU's Not Unix	SSOP	Sequence Specific Oligonucleotide Probes
GTR	Genetic Testing Registry	SSRS	Sample Storage Research Study
GvHD	Graft vs Host Disease	STAR®	Search, Tracking and Registry
HCS	HealthCare Standard	TC	Transplant Center
HCT	Hematopoietic Cell Transplantation	TED	Transplant Essential Data
HEPP	Hospital Emergency Preparedness Program	TIDES	Toolkit for Immunogenomic Data Exchange and Storage
HGDP	Human Genome Diversity Panel	TNC	Total Nucleated Cell
HHQ	Health History Questionnaire	TSA	Transportation Security Agency
HHS	Health and Human Services	UI	User Interface
HIPAA	Health Insurance Portability and Accountability Act	UML	Unified Modeling Language
HIS	Hispanic	URD	Unrelated Donor
HLA	Human Leukocyte Antigen	WGA	Whole Genome Amplification
HML	Histoimmunogenetics Mark-up Language	WMDA	World Marrow Donor Association
HR	High Resolution	WU	Work-up
HRSA	Health Resources and Services Administration		